

FIG. 1

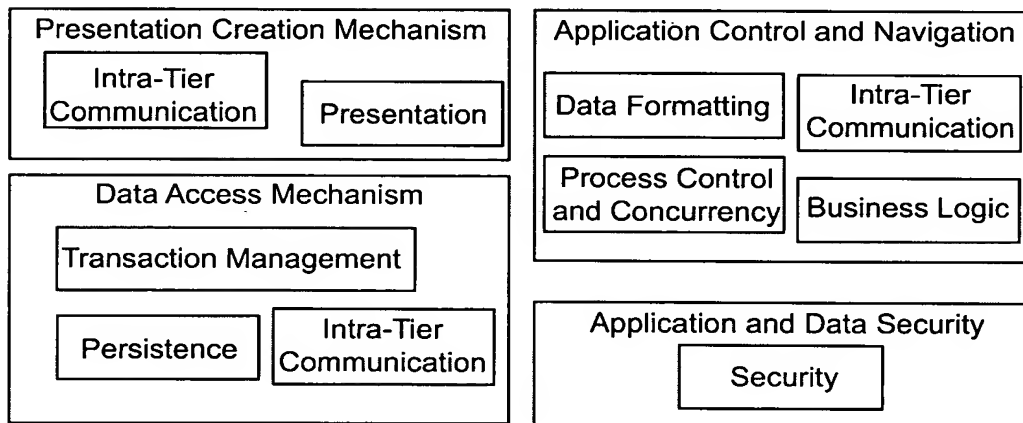
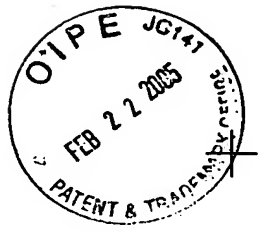


FIG. 2

+



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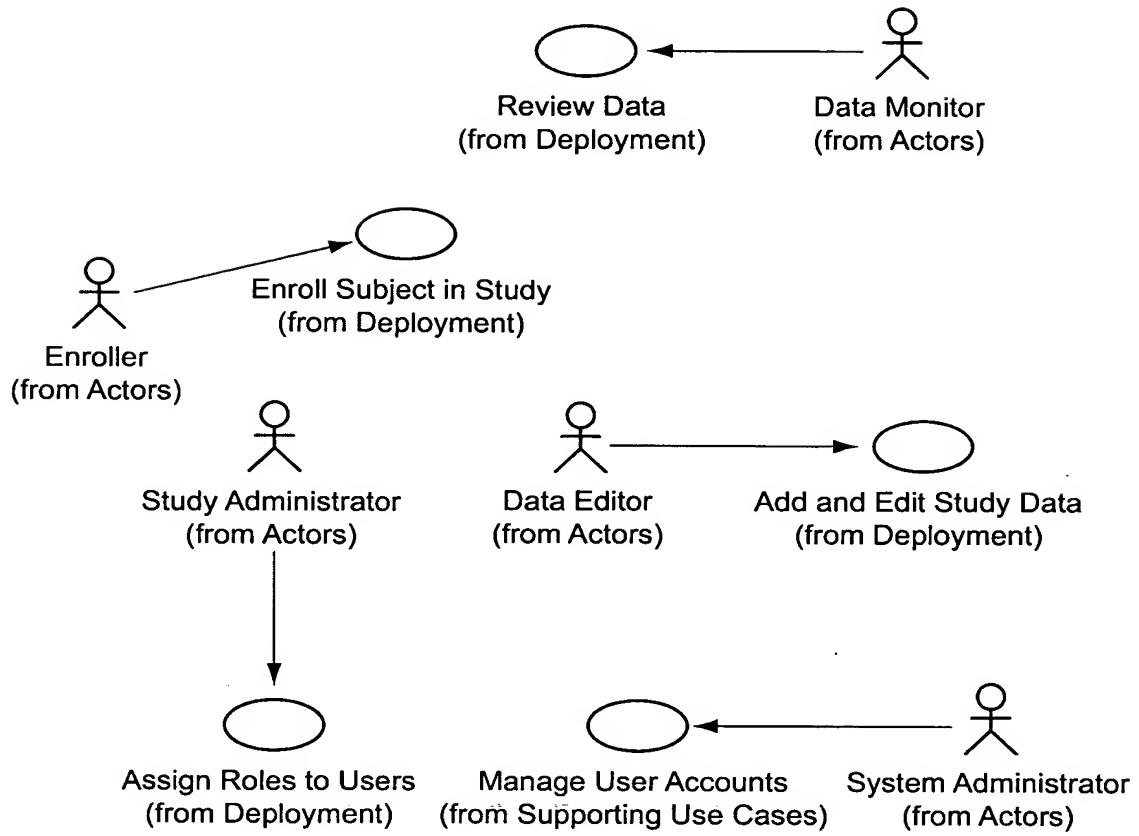
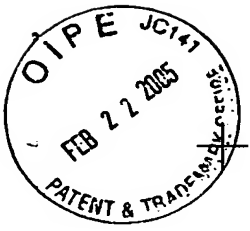


FIG. 3

+



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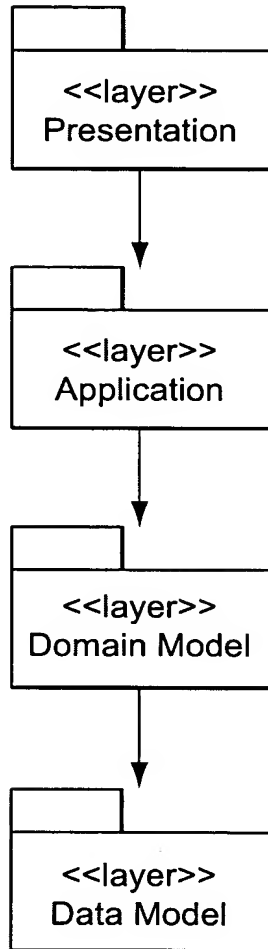


FIG. 4

+



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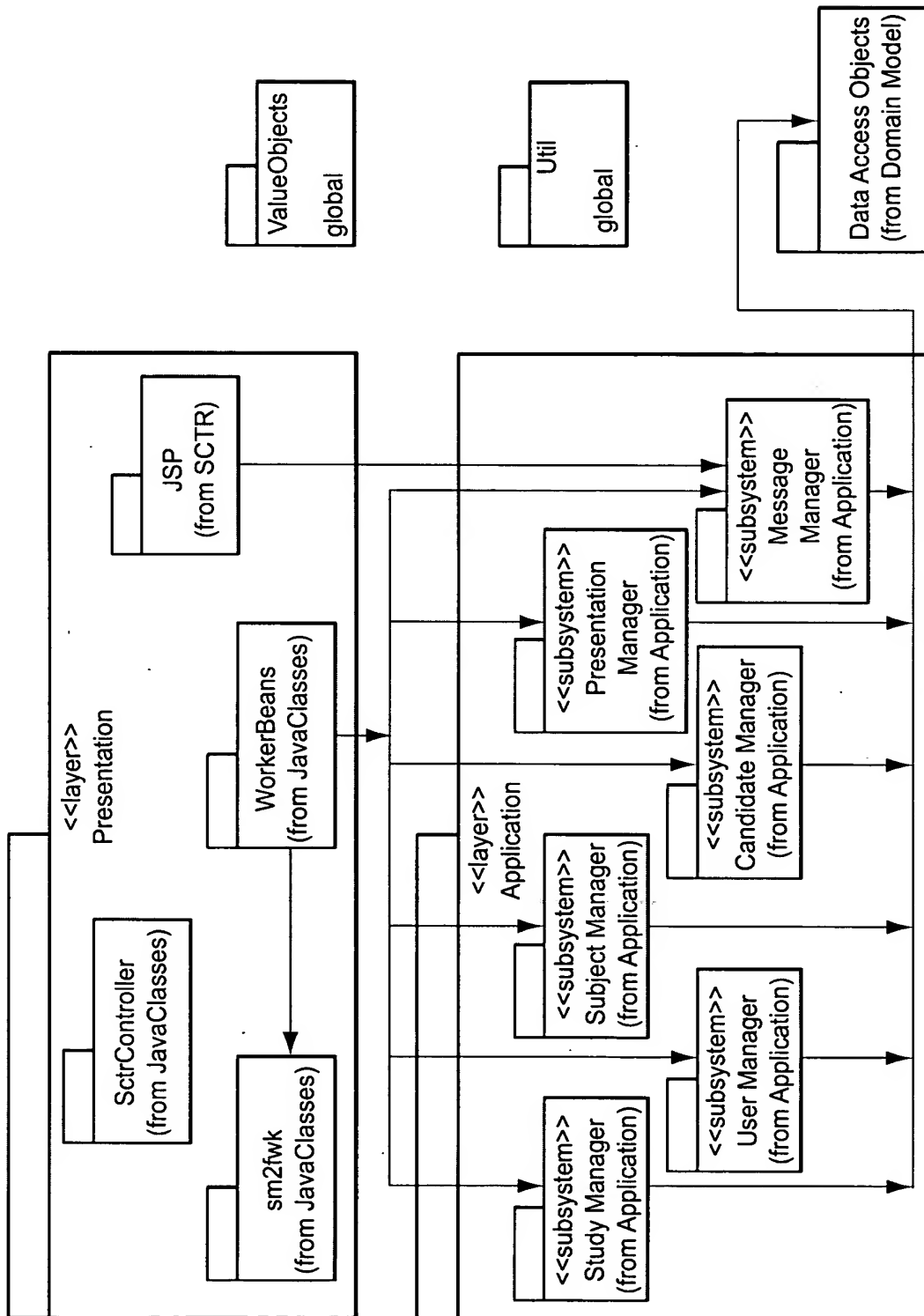
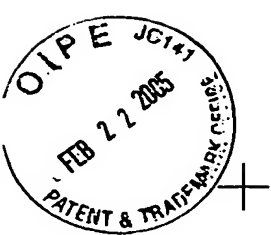


FIG. 5

+



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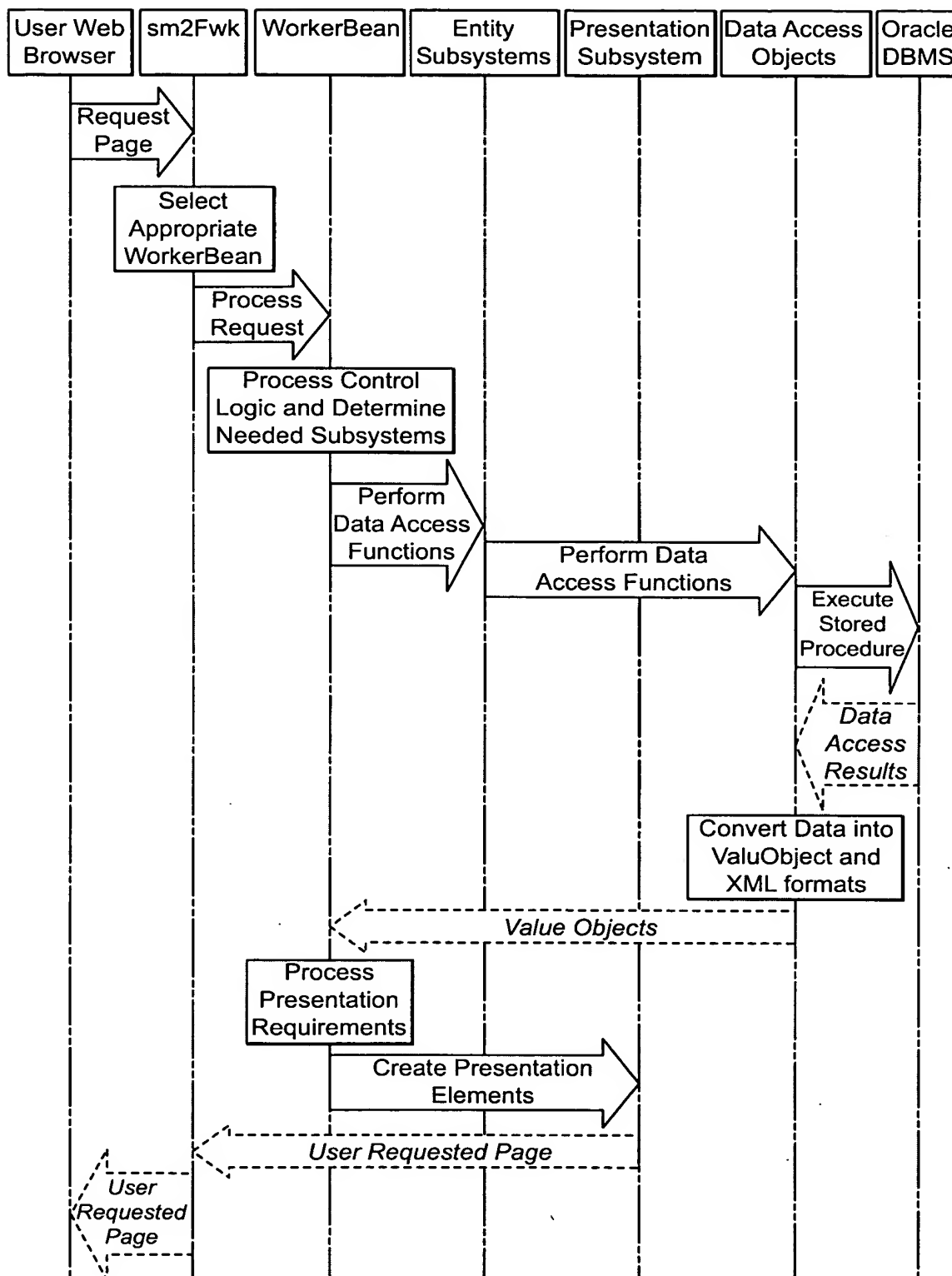
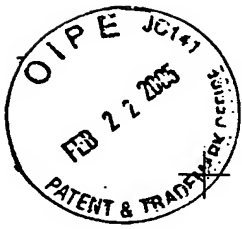


FIG. 6





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Login Function

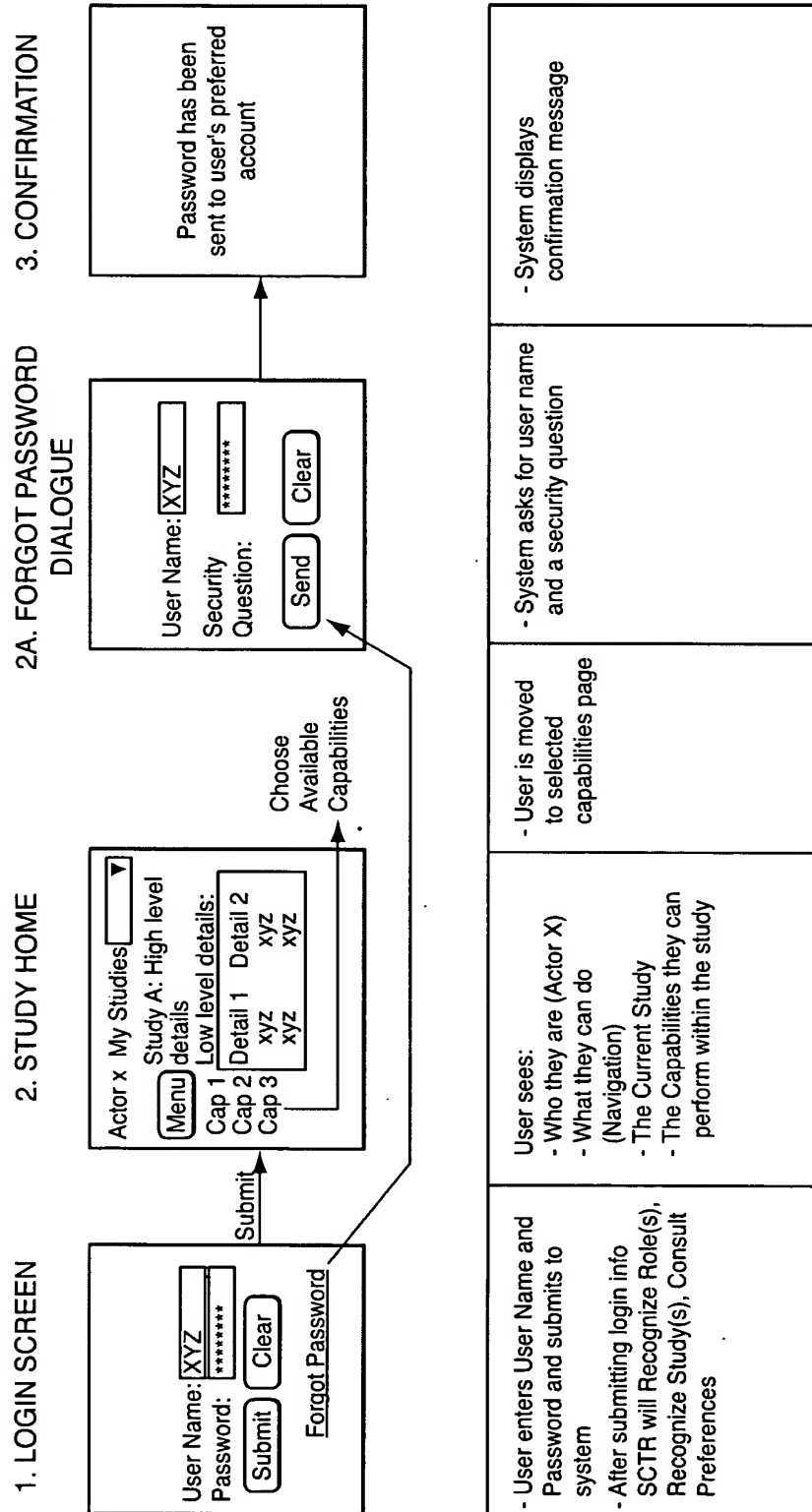
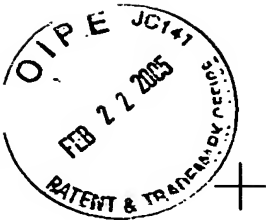


FIG. 7

+

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REPLACEMENT SHEET



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Register Candidate Subject Function

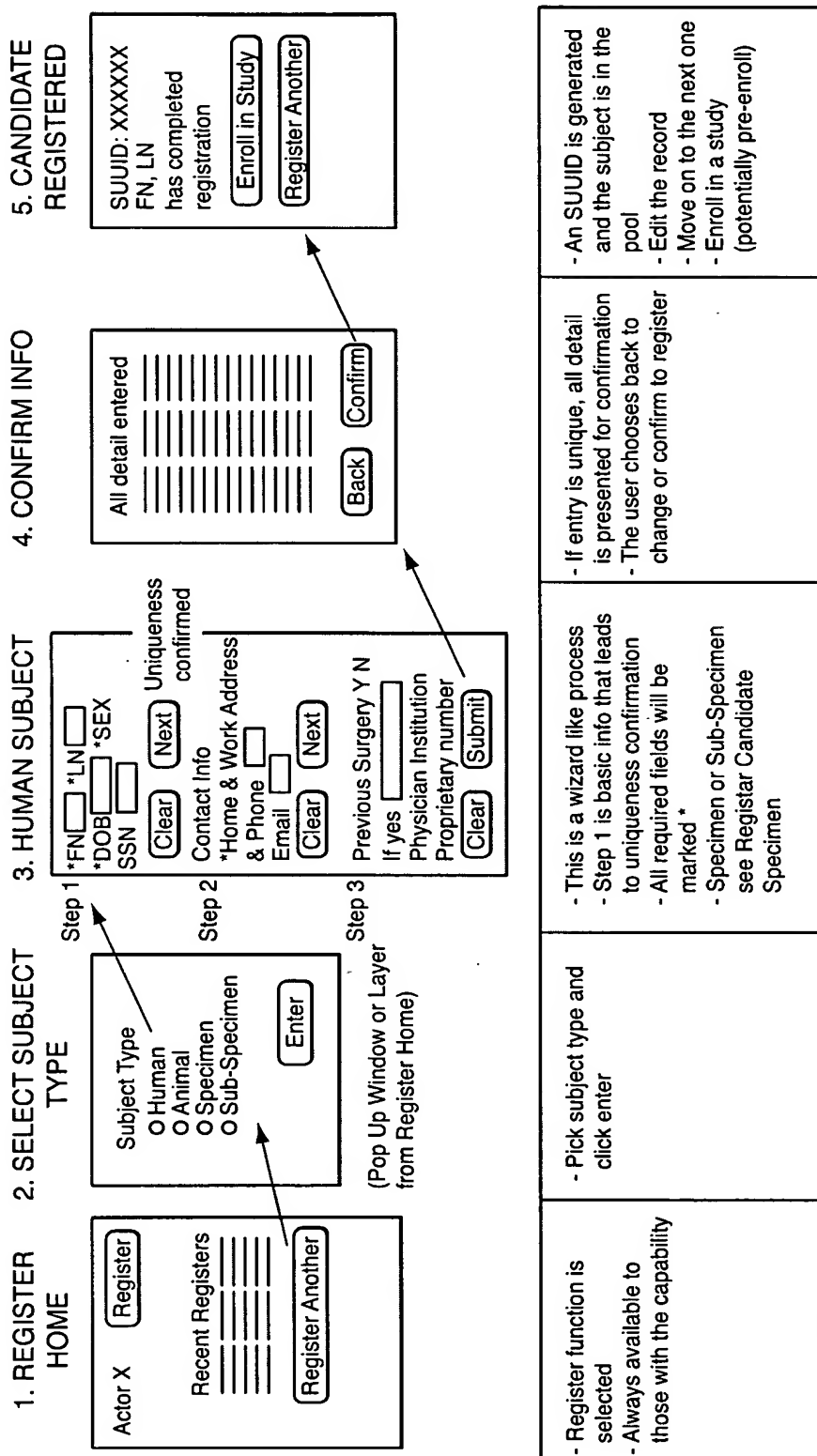
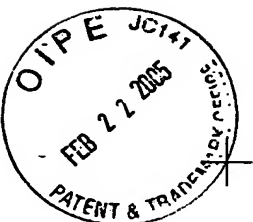


FIG. 9



Register Specimen Function

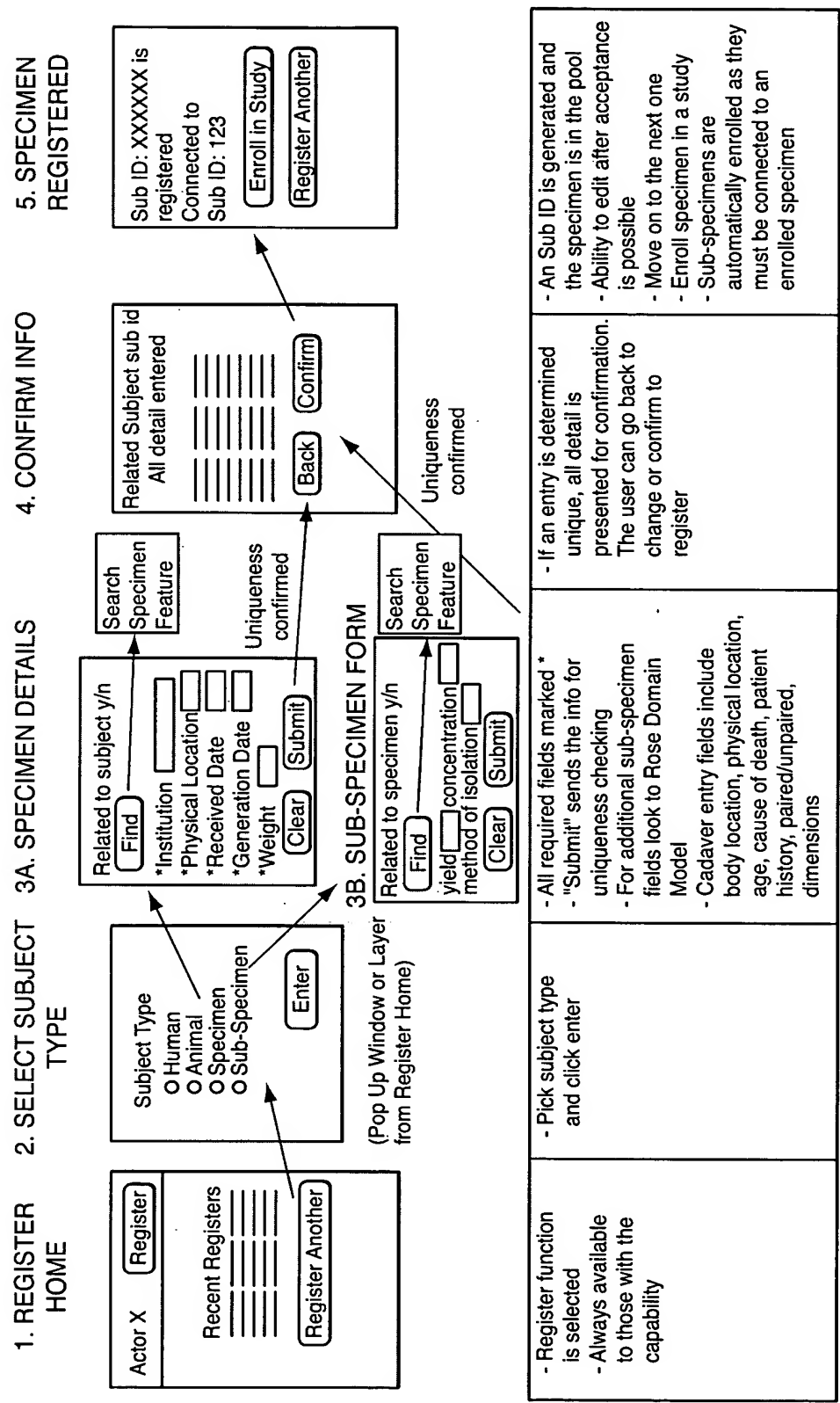
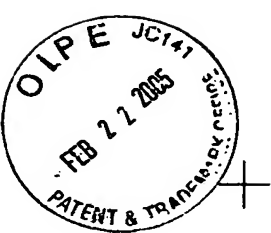


FIG. 10



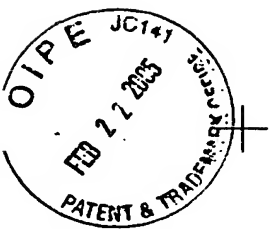


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ADVANCED SEARCH

Who I Am	Where I Am	Search (Easy, Advanced)
<div>Advanced Search</div>		
<div>Keywords:</div>		
<hr/>		
<div>PATIENT:</div>		
SUUID:	Profile Created:	
First Name:	Last Name:	
Enrollment Date:		
<hr/>		
<div>STUDY:</div>		
Study ID:	Condition:	
Study Name:	Procedure:	
Data sets:	Study Type:	
Approval Date:	Start Date of Study:	
<div>Search Clear</div>		

FIG. 11



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Open Enrollment Functions

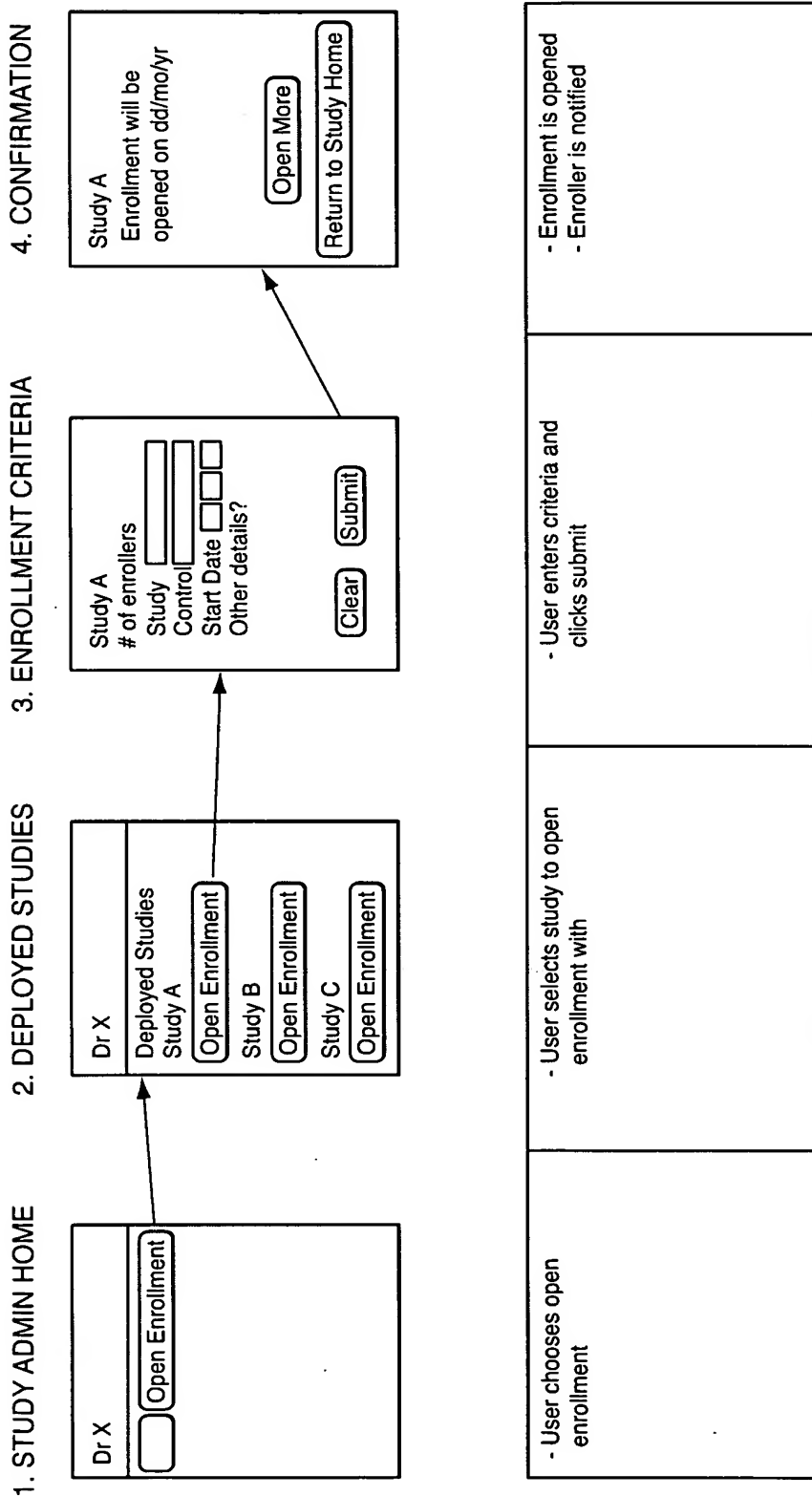
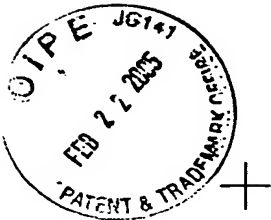


FIG. 12

+



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Close Enrollment Functions

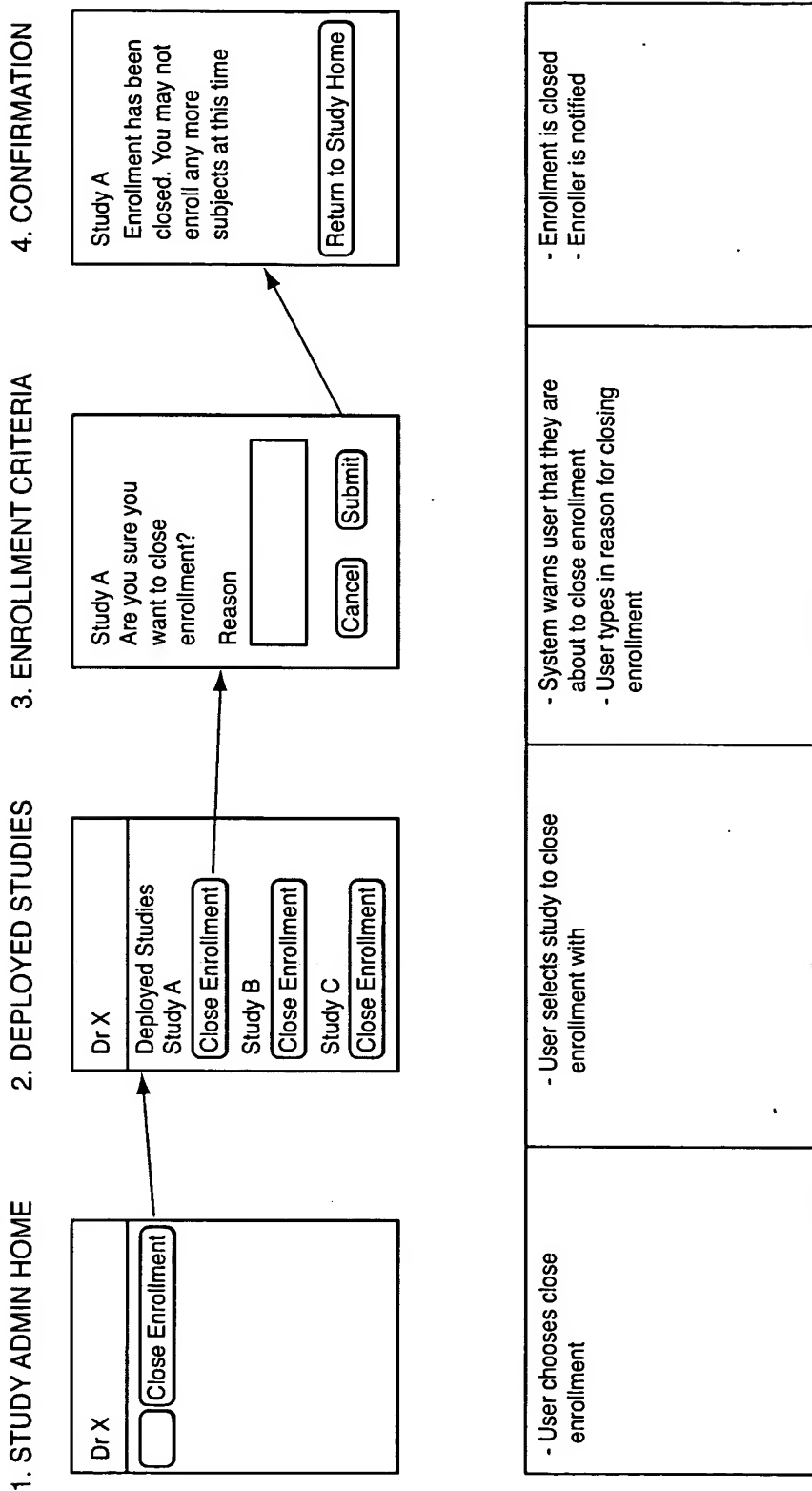
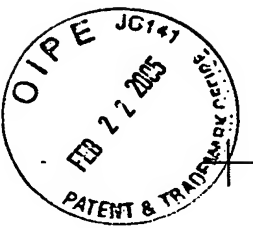


FIG. 13



Role Definition Function

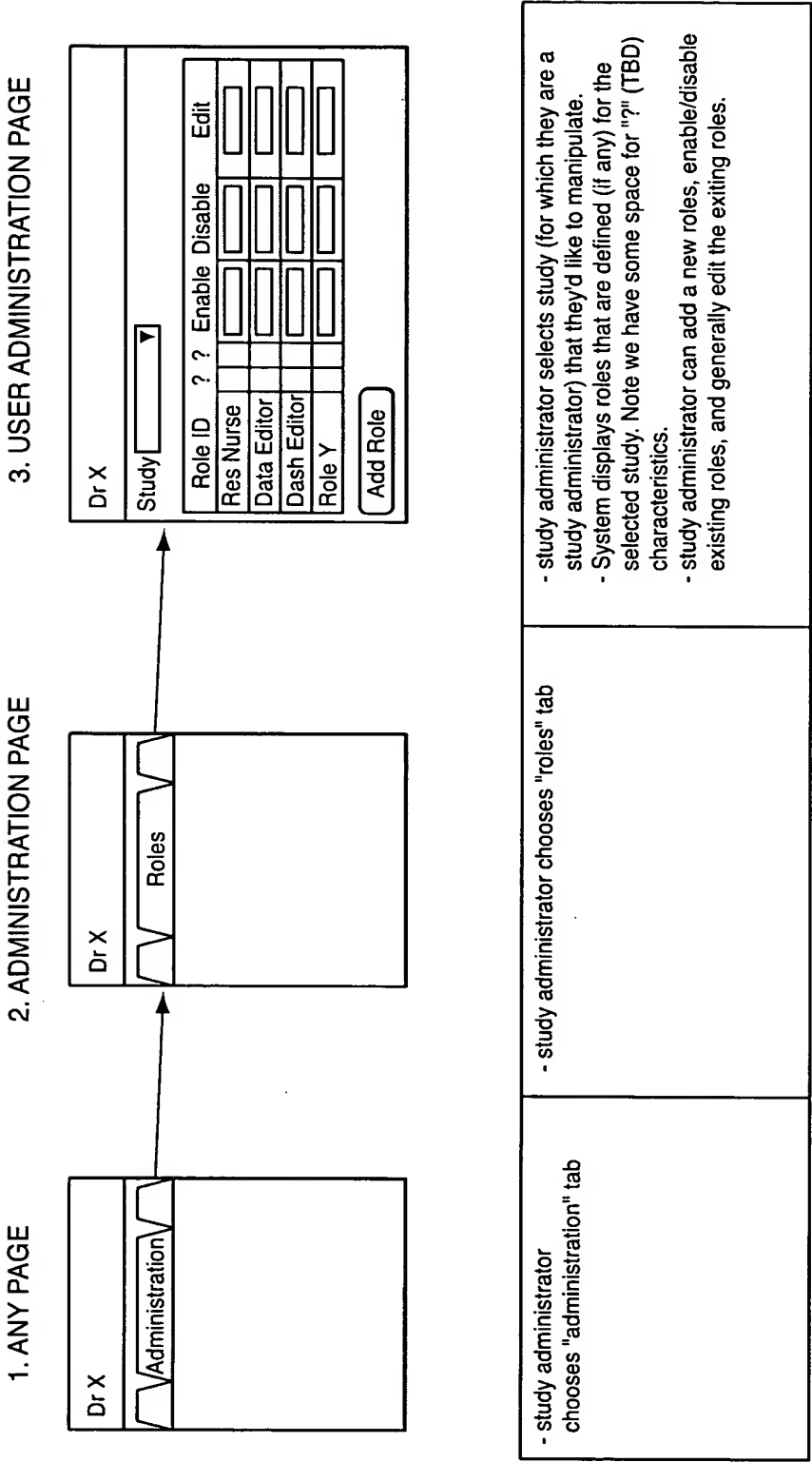
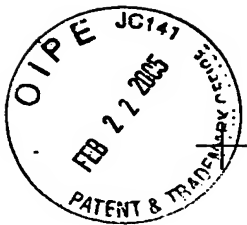


FIG. 14a

+



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Role Definition Function (Cont.)

5. CONFIRMATION PAGE

4. ROLE PAGE

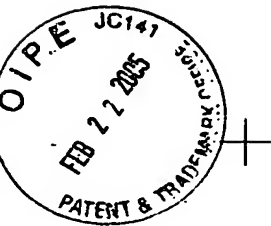
Dr X	
For Study XYZABC Role: Research Nurse 3	
Capabilities:	
Enroll Subjects:	<input type="button" value="Assign"/> <input type="button" value="Remove"/>
Disenroll Subjects:	<input type="button" value="Assign"/> <input type="button" value="Remove"/>
<input type="button" value="Submit"/>	

Changes made to study have been committed

<ul style="list-style-type: none">- study administrator selected Add Role or edit an existing role from previous page or- when study administrator selects either Assign or Remove, the system refreshes the page to indicate updated information- the <i>fault line</i> simply indicates that there are lots of capabilities and we'll need to find a nice model to reflect them.- Move discrete data-oriented capabilities like Edit Data and Review Data capabilities have a sub-table for known data sets (and the ubiquitous freeform dataset (attachment, link, or block of text).	<ul style="list-style-type: none">- System confirms Role revision / creation
---	--

FIG. 14b

+



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Role Assignment Function

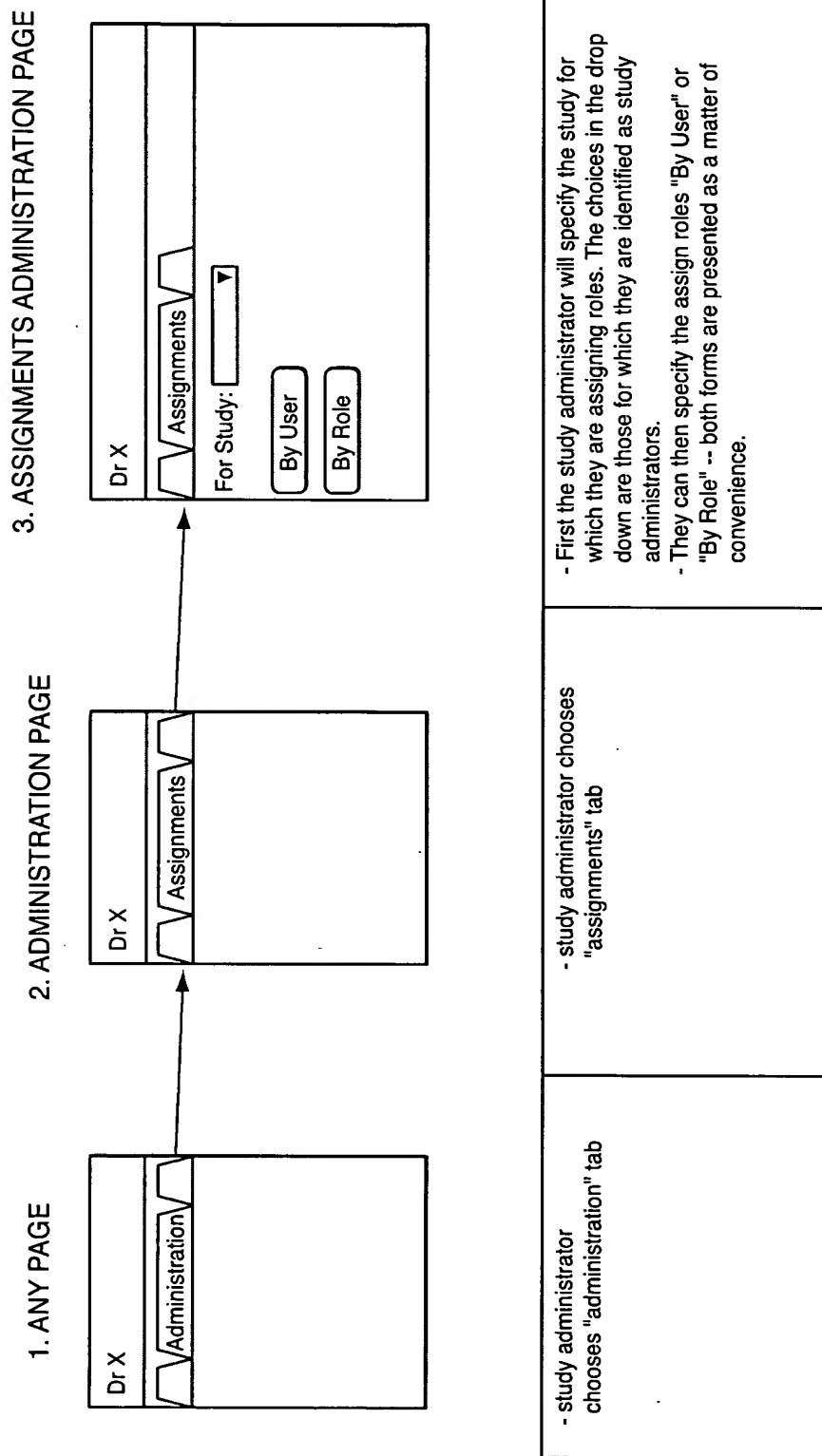
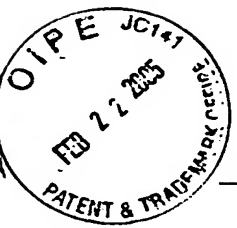


FIG. 15a



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Role Assignment Function (Cont.)

4A. ROLE ASSIGNMENT BY USER PAGE OR 4B. ROLE ASSIGNMENT BY ROLE PAGE

Dr X

Assignments

For Study: XYZABC

Apply to User:

Assigned Roles

Available Roles

Assign Remove

Submit

Dr X

Assignments

For Study: XYZABC

Role:

Users With Roles

Users Without Roles

Assign Remove

Submit

Dr X

Changes to roles have been committed

Return to Roles

<ul style="list-style-type: none">- View if study administrator selected "By User"- study administrator can Assign/Remove roles by clicking on the "Assign" and "Remove" buttons- System will refresh page when user Assigns/Removes Roles	<ul style="list-style-type: none">- View if study administrator selected "By Role"- A study administrator can Assign/Remove roles by clicking on the "Assign" and "Remove" buttons (assigning users to the roles)- System will refresh page when user Assigns/Removes Roles	<ul style="list-style-type: none">- System confirms Role assignments
--	---	--

FIG. 15b

User Administration Function

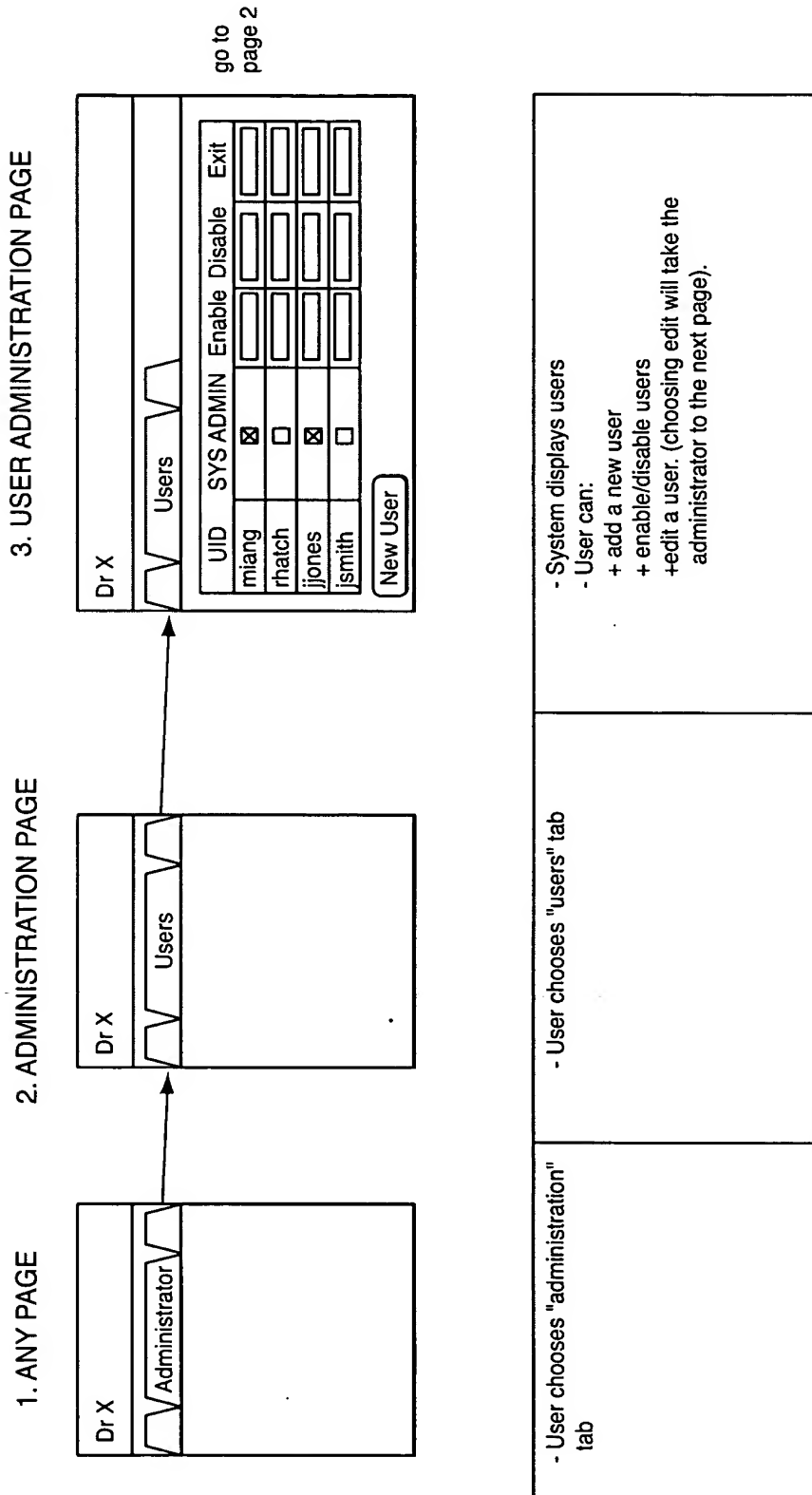
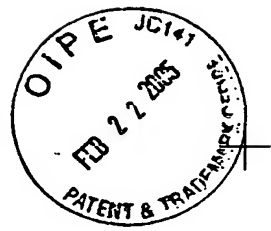
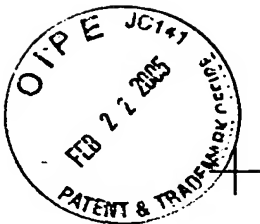


FIG. 16a

+



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Subject Enrollment Function

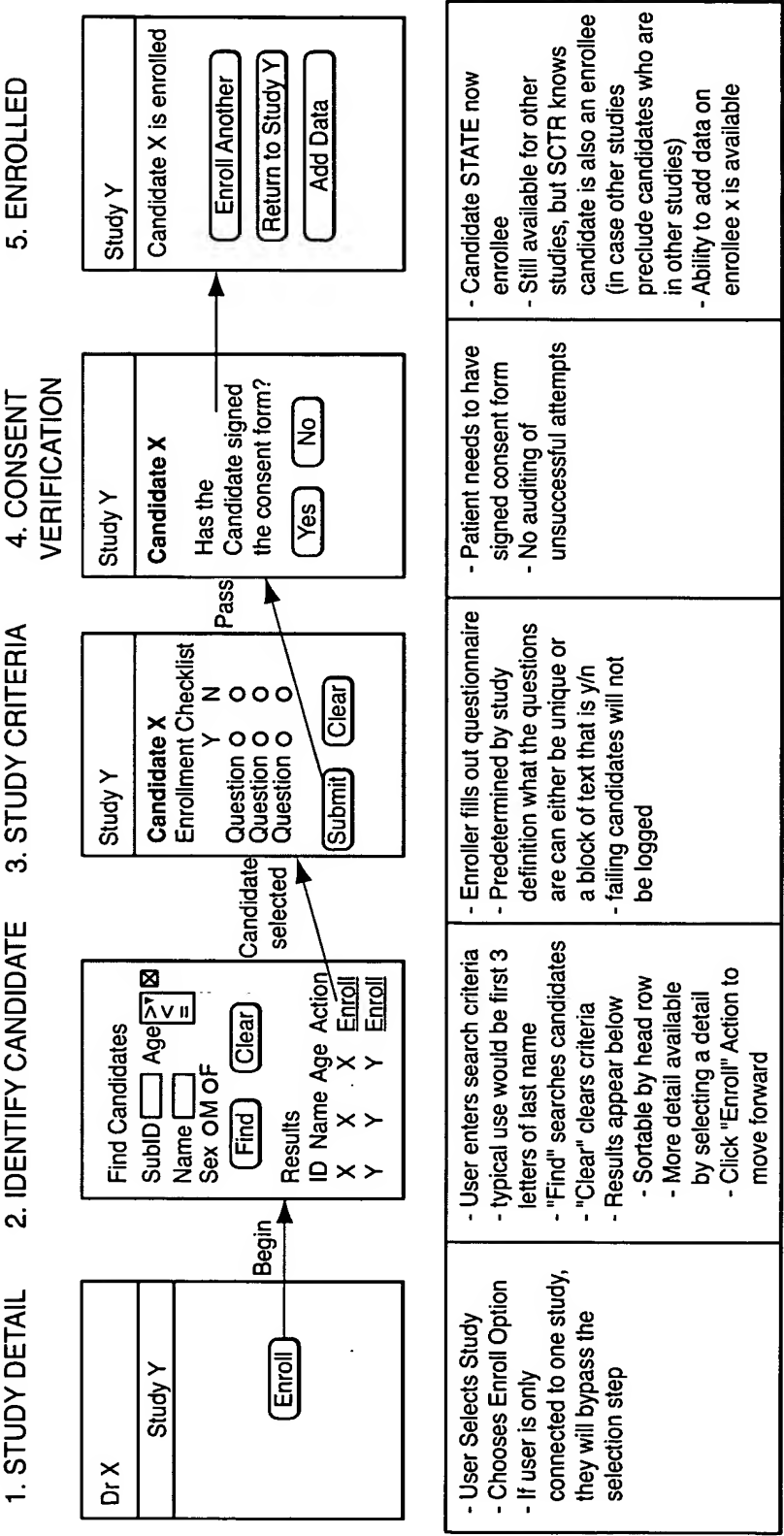


FIG. 17



Add/Edit Study Data Functions

1. STUDY HOME 2. DETAIL VIEW 3. ADD DATA ITEMS 4. CONFIRM DATA SET 5. SUMMARY VIEW 5. SUMMARY VIEW UPDATED

[illegible]

Select Data Set

- | | | | | |
|--|--|--|---|---|
| <ul style="list-style-type: none"> - User Selects Detail 1a from Study A list - High level details are displayed for the study (eg: Start Date, Status, description) - Low level details are displayed as well (eg: Enrollee, Last/Next Event) - Detail row is sortable, Details are selectable - User can change study by selecting it in the "My Studies" dropdown list | <ul style="list-style-type: none"> - User selects Enrollee Detail 1A - Hyperlinked Breadcrumb trail - User can only edit/view what they have access to - Likely Details include: <ul style="list-style-type: none"> - DataSet Name - Last Modified - Status - Action - User will be able to click on details to show deeper details | <ul style="list-style-type: none"> - User can add items to the Data Set (see Data Methods Lower Left) - Could "Append" data (unscheduled data collection) - List all events chronological with perhaps an ability to sort by datasets, status | <ul style="list-style-type: none"> - System confirms Data Set Change/Addition - User Clicks OK if info is correct | <ul style="list-style-type: none"> - Enrollee Data Set updated |
|--|--|--|---|---|

FIG. 18



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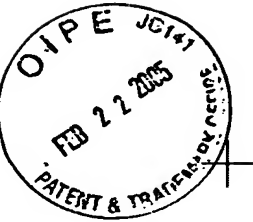
Add/Edit Genetics Data Functions

1. FIND SUBJECT 2. DETAIL VIEW 3. EDIT DATA ITEMS 4. CONFIRM DATA SET 5. SUMMARY VIEW UPDATED

Study Selected (A) <input type="text"/> Enter Subject ID <input type="text"/> Find Related Subject Subsets Subset Detail A Action Sample a Edit Protein a Edit Register Another	Study Selected (A) History: Current Activity Sample Description Detail A Detail B Status Action 1a 1b 1c 2a 2b 2c 3a 3b 3c Edit Edit Edit Select Sample	Study Selected (A) Detail (1A) History/History: Current Activity Data Set (1A) Form Entry or File Upload Q A Desc 0000 0000 0000 Clear Submit	Data Item Confirmation Summary OK Cancel	Study Selected (A) Related Subject Subsets Subset Detail A Action Sample a Edit Protein a Edit Register Another
--	--	---	---	--

- User searches for Subject (Specimen) with Study - Related Specimens and subsets shown - User selects subject subset - Detail row is sortable, Details are selectable - User can change study by selecting it in the "My Studies" dropdown list - If the specimen subset is not found, the ability to register another is available (see Register Specimen Subset)	- User selects Sample - User can only edit/view what they have access to - Likely Details/Characteristics include: - Data Set Name - Date of Collection - Location (freezer, shelf, rack, box, position) - Status - Action - User will be able to click on details to show deeper details	- User can add items to the Subset (see Data Methods Lower Left) - Could "Append" data (unscheduled data collection) - List all events chronological (last event first) with perhaps an ability to sort by datasets, status	- System confirms Data Set Change/Addition - User Clicks OK if info is correct	- Subject Subset List Updated
--	--	---	---	-------------------------------

FIG. 19



Review Data Functions

3. REVIEW DATA ITEMS

2. DETAIL VIEW

1. STUDY HOME

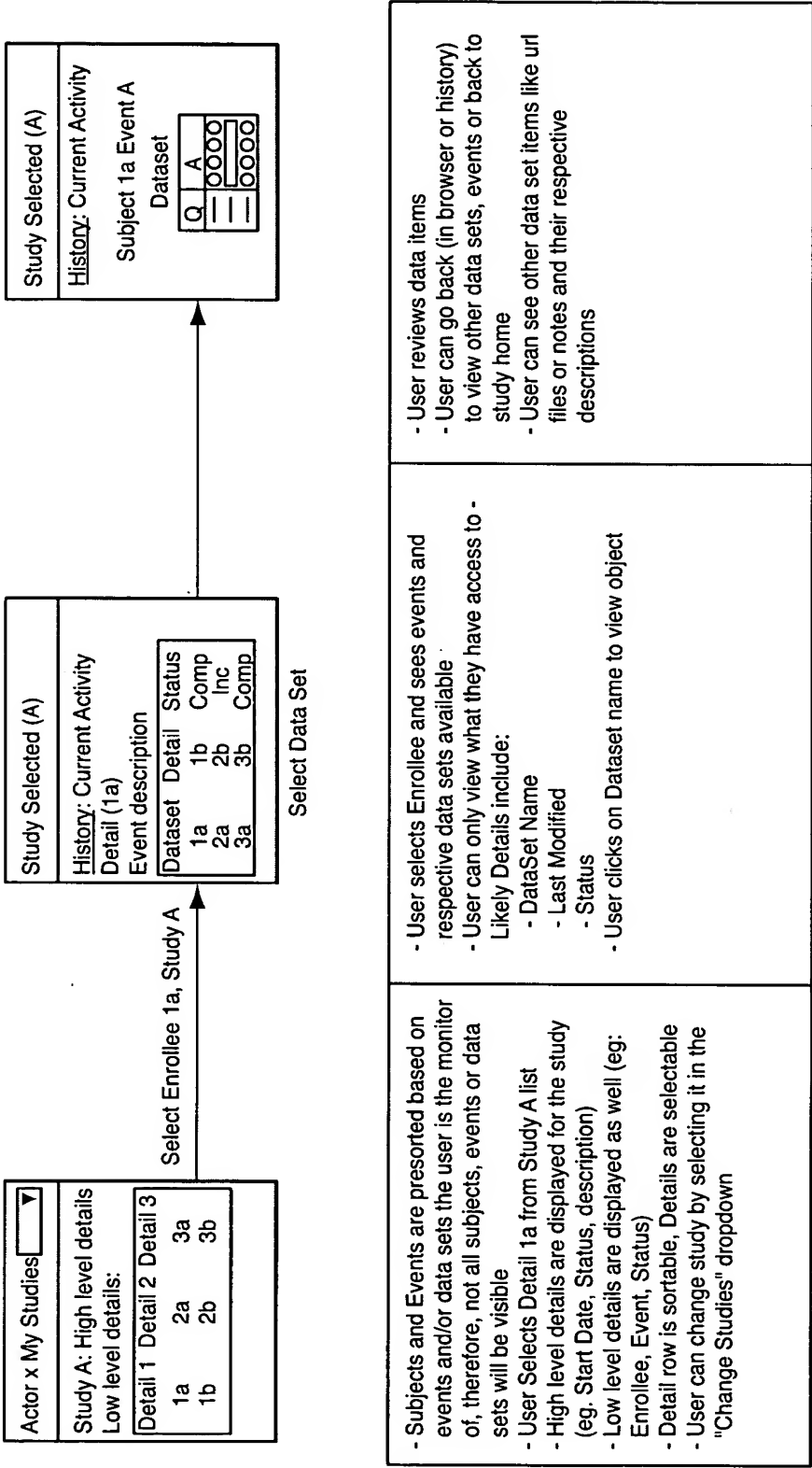
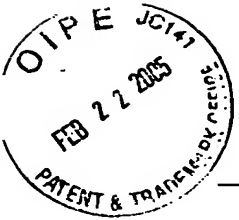


FIG. 20





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Approve Data Functions

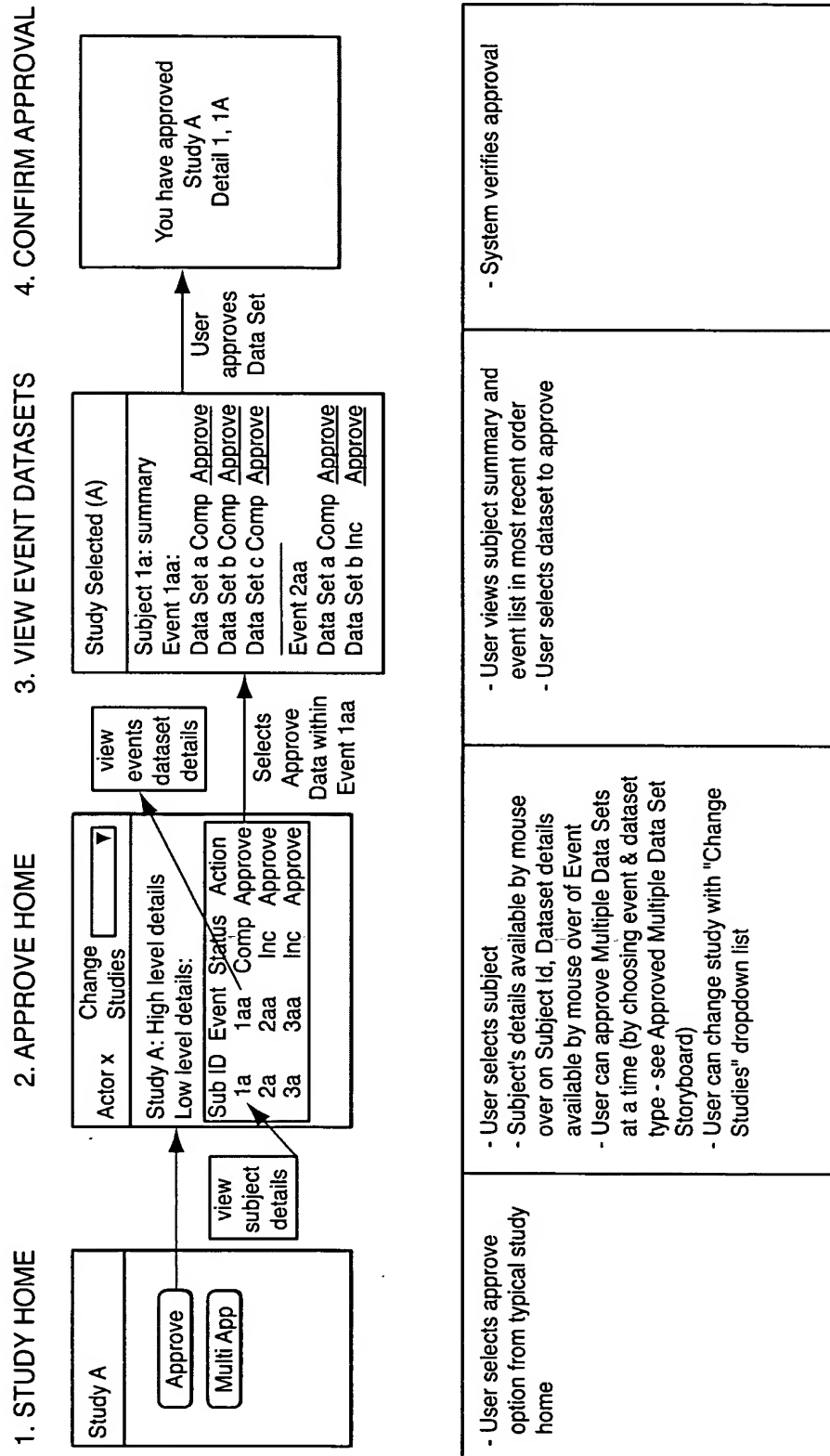
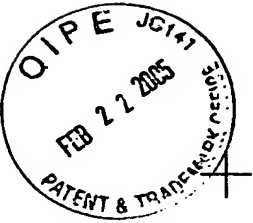
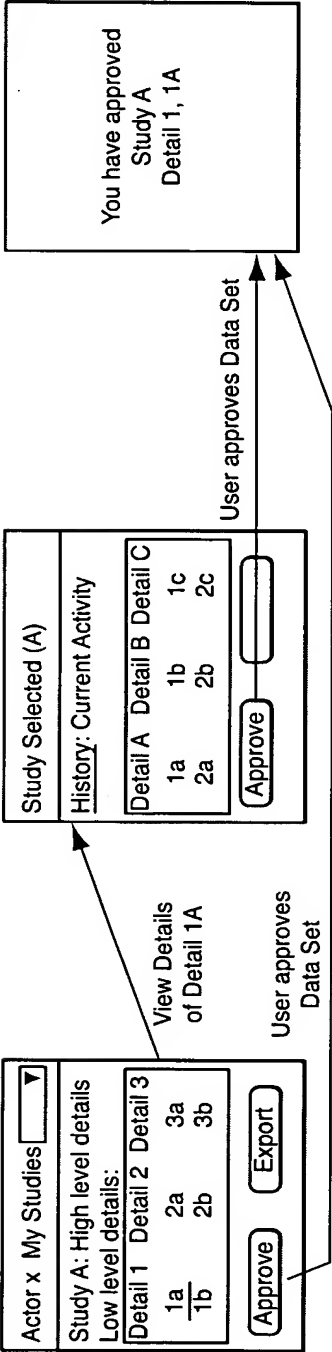


FIG. 21



Approve (freeze) Data Set Functions

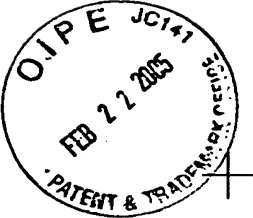
- 1. TAILORED HOME PAGE
- 2. VIEW DETAILS
- 3. CONFIRM APPROVAL



<ul style="list-style-type: none">- User sees current study and the subjects enrolled in that study- User can approve Data Sets from this page- User can approve Multiple Data Sets at a time- User can change study by selecting it in the "My Studies" dropdown list- User can export data for analysis in an external tool	<ul style="list-style-type: none">- User can view details of a Subject- User can approve data from this page	<ul style="list-style-type: none">- System verifies approval
---	---	--

FIG. 22





Reinstate Function

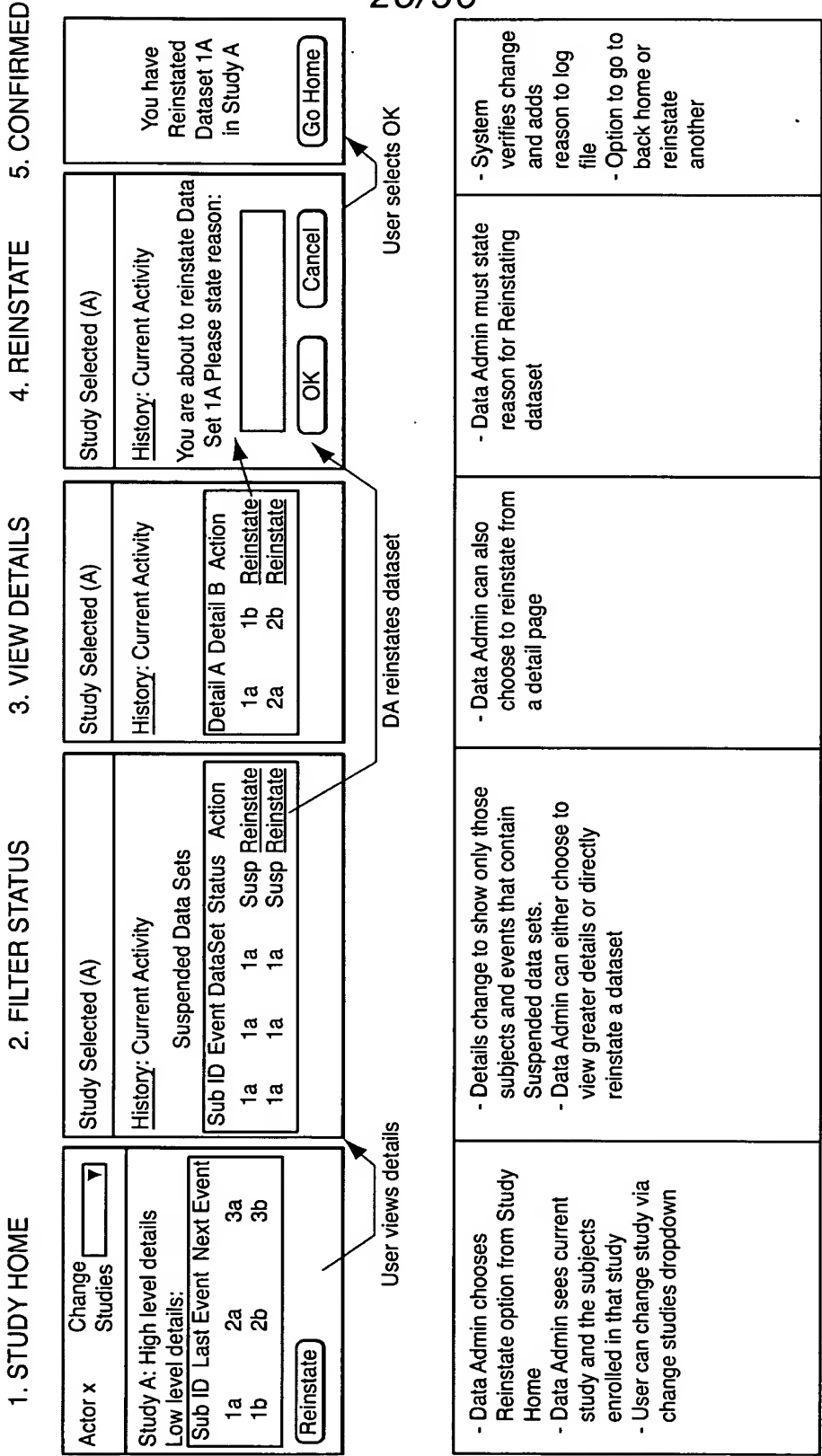
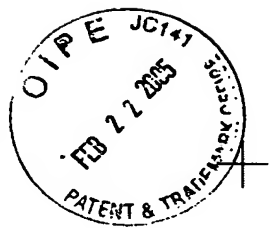


FIG. 23





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SCCTR

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ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

SCCTR Mail

Preferences

Help

Logout

Search:

Last Name

go

Back To

--Select a Study--

go

Post Message

For: Everyone

Study: Fracture Callus

Title:

Message:

Priority: Normal

Clear

Post

View Messages

To sort alerts, click on the column header that you wish to sort on.

Study: Basal Joint Arthritis

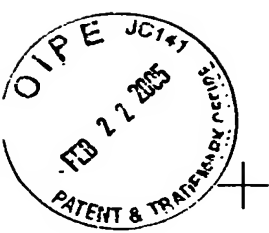
Date	User	Title	Priority
09/30/2001	hotchkiss	Enrollment for Basal Joint Arthritis Closed	High
09/11/2001	twright	Subject 457342 is disenrolled for study	High
07/23/2001	lariola	Subject 123442 is disenrolled for study	High
08/12/2001	hotchkiss	Collaborator Walter Reed data Set Editability Suspended	Normal
06/18/2001	hotchkiss	Subject 123442 is disenrolled for study	Alert
09/23/2001	twright	Enrollment Closed for Basal Joint Arthritis Study	Normal
09/11/2001	lariola	Subject 123442 is disenrolled into study	Low
07/23/2001	hotchkiss	Collaborator TIGR data set editability has been Reinstated	Normal


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Hospital for Special Surgery
Problems?
SCTR Administrator
John Doe

[Legal Notices](#)

FIG. 24







SPONSORED BY THE
ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

SCTR Mail Preferences | Help | Logout

Search:

Last Name

SCTR Mail Message Center

SCTR Mail Home

Back To

--Select a Study--

Post Message

For:

Study:

Title:

Priority:

View Message

Date: 09/30/2001

From: rhotchkiss

Priority: High

Title: Enrollment for Basal Joint Arthritis Closed

Message:
Enrollment for the Basal Joint Arthritis Study #445599 has been closed as of 12:30pm 09/20/2001. The maximum number of subjects have been enrolled - we have no further need for subjects at this time.

Previous Message

Next Message

Archive Message

Close Window

08/12/2001 rhotchkiss Collaborator Walter Heed data Set Editability Suspended

06/18/2001 rhotchkiss Subject 123442 is disenrolled for study

09/23/2001 twilight Enrollment closed for Basal Joint Arthritis Study

09/11/2001 lariola Subject 123442 is disenrolled for study

07/23/2001 rhotchkiss Collaborator TIGR data set editability has been Reinstated

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Hospital for Special Surgery
Problems?
SCTR Administrator
John Doe

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Priority

High

High

High

Normal

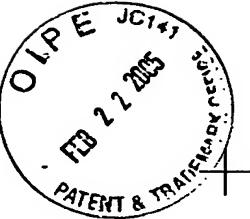
Alert

Normal

Low

Normal

FIG. 25



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SPONSORED BY THE
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SCTH

User: Robert Hotchkiss, MD

SCTH Mail Preferences | Help | Logout

Search:

Last Name

Study Home

Manage Subjects

Reports

Administration

Register

Study: 445599 Basal Joint Arthritis

Manage Subjects Home

Change Studies

View All Studies

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

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Problems?
SCTR Administrator
John Doe
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Enrolled Subject View

Subject ID	First Name	Last Name	Sex	Age	Last Event	Status	Last Event Date	Next Event
123456	Mary	Smith	F	22	Initial visit	Comp	09/11/2001	Surgery
123455	Brenda	Heidelberg	F	32	Initial visit	Inc	09/11/2001	Surgery
123454	Helga	Rothchild	F	48	Initial visit	Inc	09/11/2001	Surgery
123453	Donna	Donaldson	F	67	Surgery	App	09/19/2001	1-Mon Postop
123452	Flora	Dorfman	F	79	1-Mon Postop	Inc	09/11/2001	3-Mon Postop

Total number of enrollees: 27

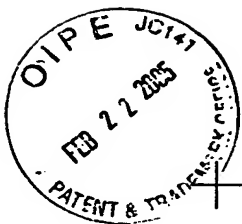
Scheduled Event Status View

EVENT	DATA ENTRY STATUS			
	TBE	Incomplete	Complete	Approved
Initial Visit	18	22	5	3
Surgery	4	5	12	9
1-Mon Postop	12	12	3	2
3-Mon Postop	2	3	2	1
3-Mon Postop	3	0	0	0
1-Yr Postop	3	0	0	0
2-Yr Postop	3	0	0	0

FIG. 26

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REPLACEMENT SHEET



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SCCTR

SPONSORED BY THE
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User: Robert Hotchkiss, MD

Search:

Last Name

go

SCTR Mail | Preferences | Help | Logout

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Add Unscheduled Event Confirmed
Subject 123456

Add Unscheduled Event Confirmed

The Unscheduled Event Thumb Check-up has been successfully added.

Study: 445599 Basal Joint Arthritis
Subject ID: 123456

Return to Subject View

Return to Event View

Change Studies

View All Studies go

Manage Subjects

Candidates

Find

Enroll

Enrolled View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

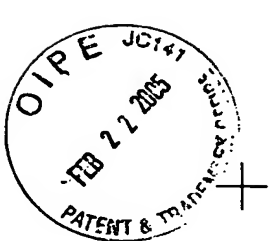
Edit

Approve

Retract Approval

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Hospital for Special Surgery
Problems?
SCTR Administrator
John Doe
Legal Notices

FIG. 29



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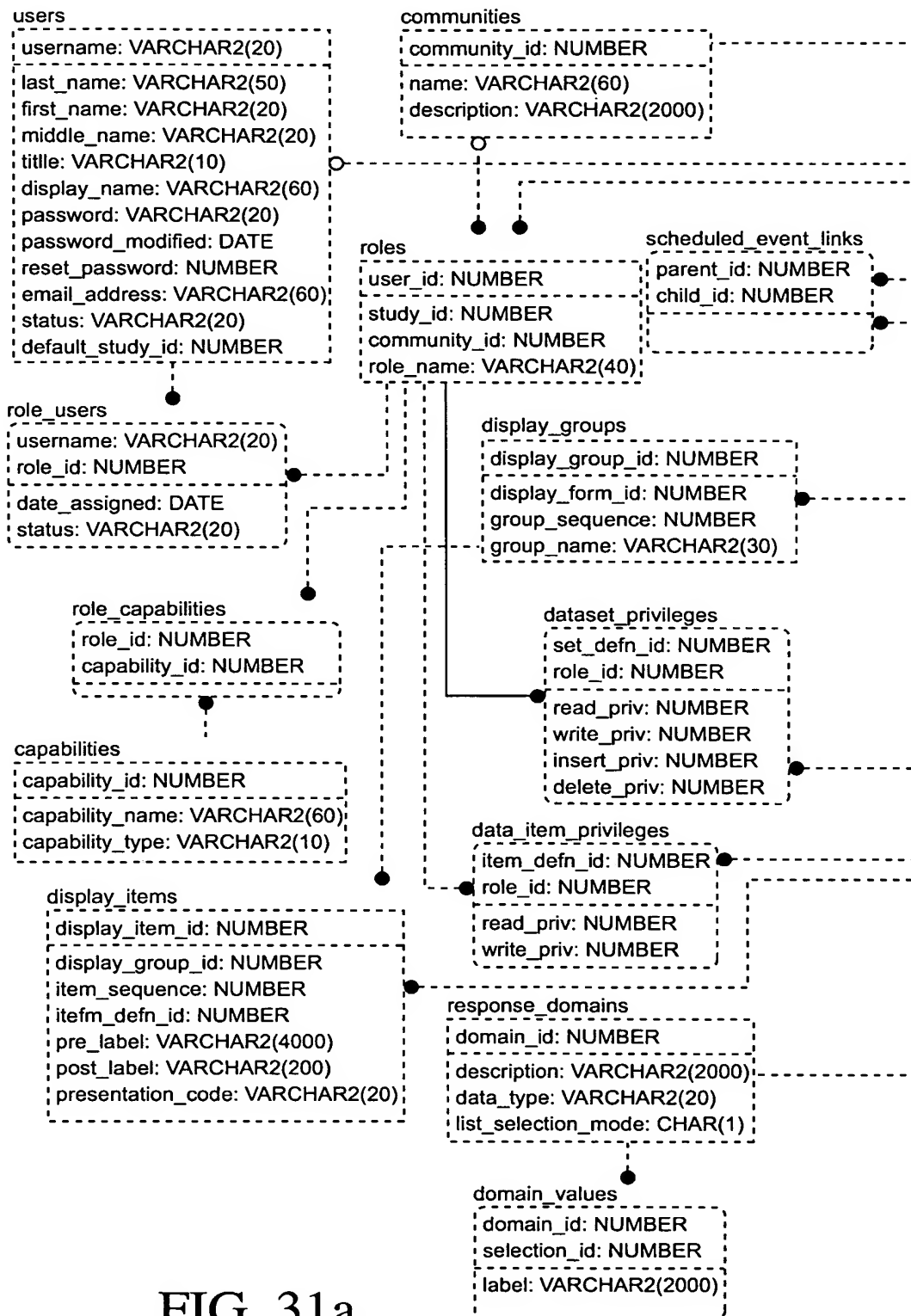


FIG. 31a

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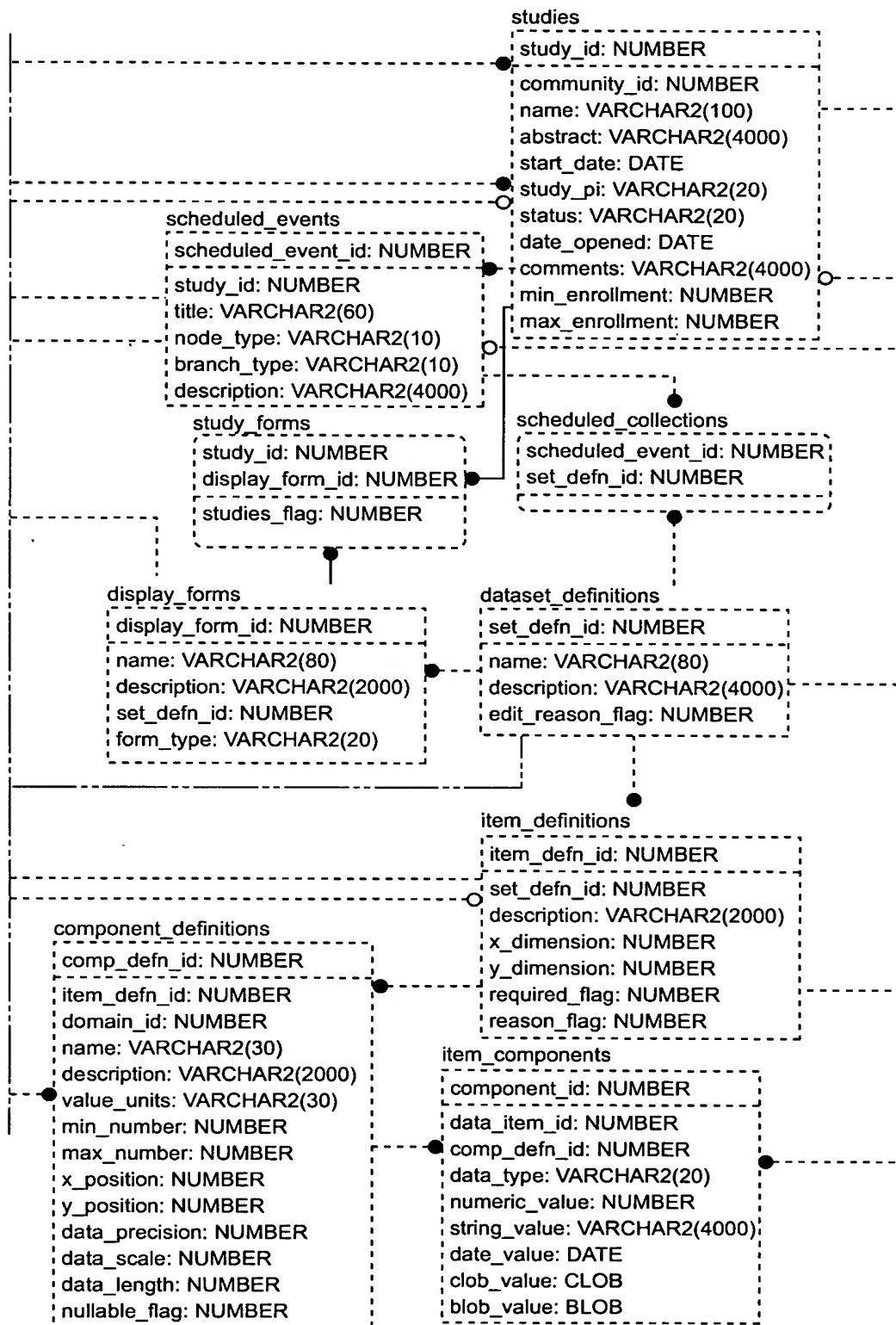
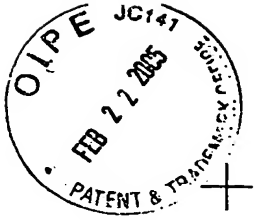


FIG. 31b



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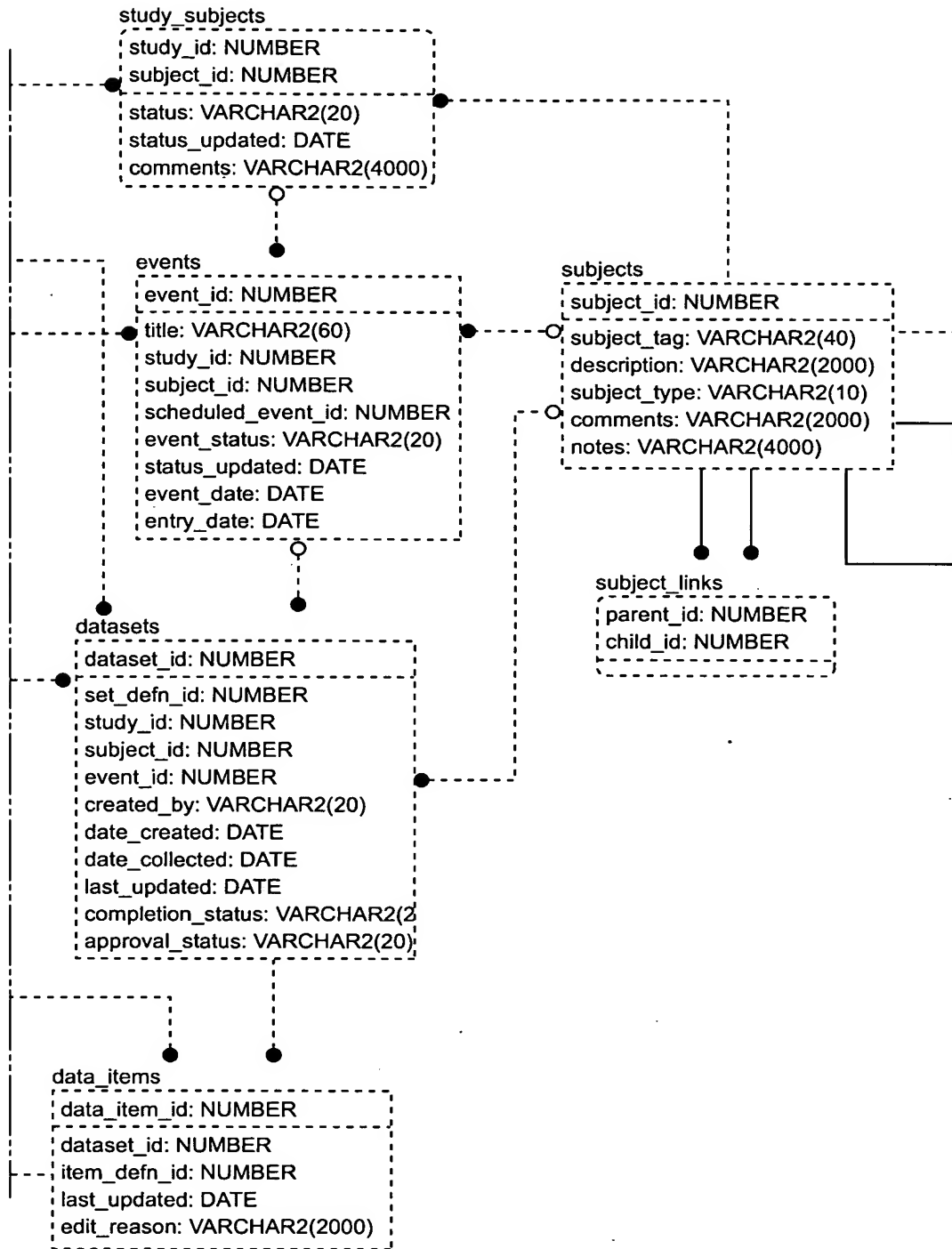
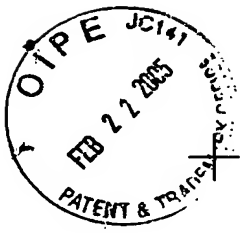


FIG. 31c





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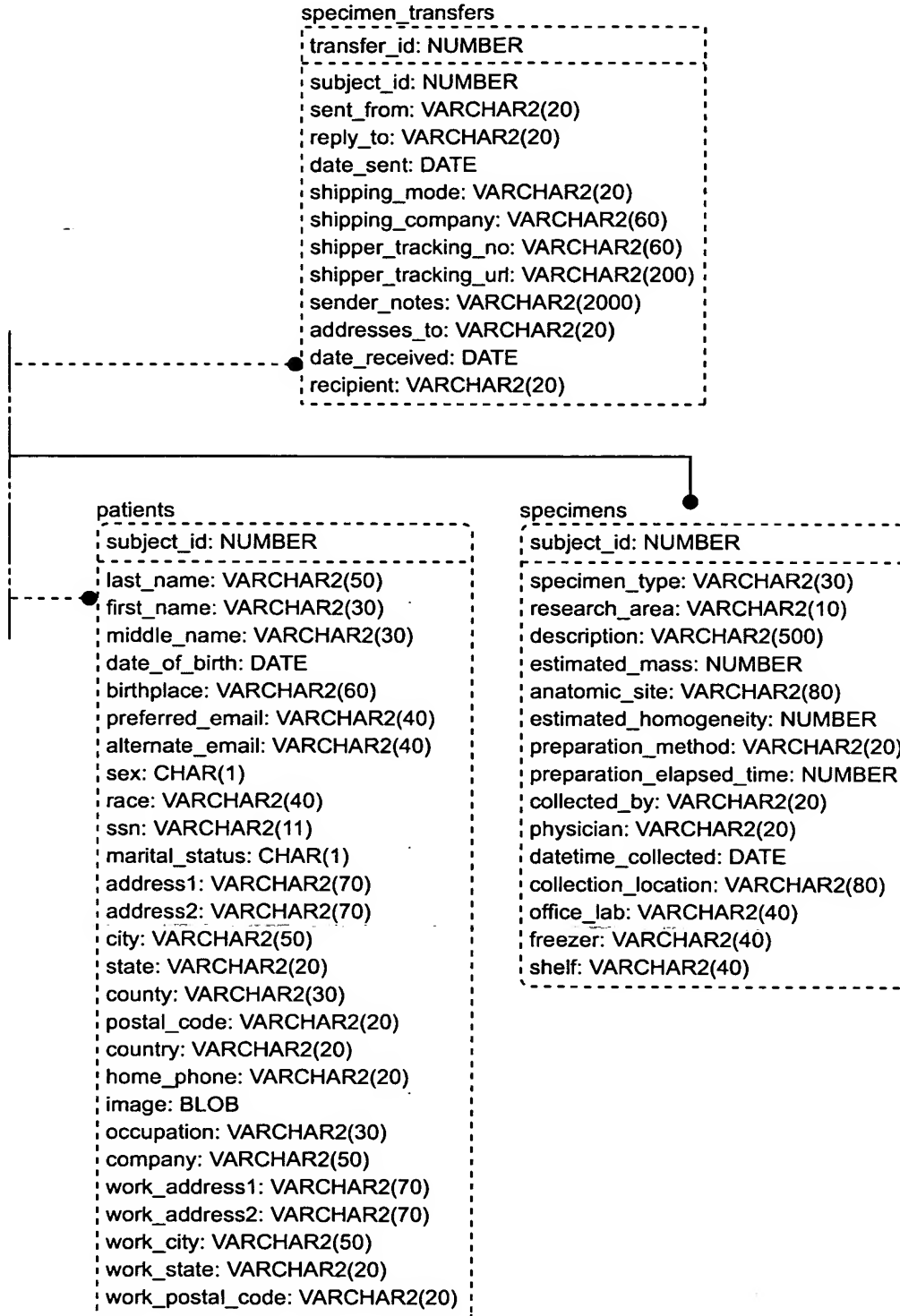


FIG. 31d

